

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

This Document Relates to All Actions

**DEFENDANTS TORRENT PHARMACEUTICALS LTD. AND
TORRENT PHARMA, INC.'S MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL
SUMMARY JUDGMENT**

TABLE OF CONTENTS

INTRODUCTION1

ARGUMENT1

I. PLAINTIFFS HAVE NOT DEMONSTRATED THAT TORRENT
MADE A MATERIAL MISREPRESENTATION.....1

II. PLAINTIFFS HAVE NOT ESTABLISHED THAT TORRENT
ACTED WITH SCIENTER.5

III. PLAINTIFFS CANNOT ESTABLISH THE REMAINING
ELEMENTS OF A FRAUD CLAIM AS A MATTER OF LAW.....8

CONCLUSION10

TABLE OF AUTHORITIES

Cases	Page
<i>Butler v. Juno Therapeutics, Inc.</i> , 541 F. Supp. 3d 774 (S.D. Tex. 2021).....	2
<i>Chateau Homes by RJM, Inc. v. Aucoin</i> , 97 So. 3d 398 (La. App. 5 Cir, 2012), writ denied, 98 So. 3d 872 (La. 2012).....	6
<i>Cnty. Hosp. of the Monterey Peninsula v. Aetna Life Ins. Co.</i> , 119 F. Supp. 3d 1042 (N.D. Cal. 2015).....	5
<i>Forbis v. Neal</i> , 361 N.C. 519 (2007)	6
<i>Harper v. Russell</i> , 836 A.2d 513 (Del. 2003)	2
<i>Harris v. Pfizer Inc.</i> , 586 F. Supp. 3d 231 (S.D.N.Y. 2022)	7
<i>Est. of Johnson ex rel. Johnson v. Weber</i> , 898 N.W.2d 718 (S.D. 2017).....	6
<i>Kitt v. Cap. Concerts, Inc.</i> , 742 A.2d 856 (D.C. 1999)	6
<i>Nevada Power Co. v. Monsanto Co.</i> , 891 F. Supp. 1406 (D. Nev. 1995).....	3
<i>Owens v. DRS Auto. Fantomworks, Inc.</i> , 288 Va. 489 (2014)	6
<i>Seibert v. Noble</i> , 499 N.W.2d 3 (Iowa 1993)	6
<i>Trana Discovery, Inc. v. S. Rsch. Inst.</i> , 915 F.3d 249 (4th Cir. 2019)	4

Van Buren v. Walmart, Inc.,
611 F. Supp. 3d 30 (D. Md. 2020), *aff'd*, 855 F. App'x 156
(4th Cir. 2021).....2

Wilson v. Dryvit Sys., Inc.,
206 F. Supp. 2d 749 (E.D.N.C. 2002), *aff'd*, 71 F. App'x 960
(4th Cir. 2003).....3

INTRODUCTION

Having seemingly recognized that they have no evidence of knowledge or scienter as to Torrent dating back to June 2018, Plaintiffs now advance the argument that Torrent engaged in fraud from August 3, 2018, the date that ZHP first informed Torrent that NDMA was found in Valsartan API manufactured using the “Old Process,” to August 17, 2018, the date that Torrent initiated its first recall of its VCDs. In arguing that Torrent is liable for fraud as a matter of law, Plaintiffs cite zero case law, misrepresent facts, and all but ignore key elements of a fraud claim. The reality is that Plaintiffs cannot establish as a matter of law that Torrent made a misrepresentation, let alone a material one, that Torrent had the requisite scienter, that anyone relied on Torrent’s alleged knowing material misrepresentations, or that Torrent’s alleged misrepresentations caused any cognizable harm. Plaintiffs’ motion should be denied.

ARGUMENT

I. PLAINTIFFS HAVE NOT DEMONSTRATED THAT TORRENT MADE A MATERIAL MISREPRESENTATION.

Plaintiffs’ motion fails because Plaintiffs have not identified any material misrepresentations by Torrent. Indeed, Plaintiffs do not address the standard for materiality at all, or attempt to establish that any particular misstatement was material as a matter of law. *See* Plaintiffs’ Brief in Support of Motion for Partial Summary Judgment on Fraud Against Torrent (“Pl. Br.”) at 3-4 ([ECF No. 2559-1](#));

see Butler v. Juno Therapeutics, Inc., 541 F. Supp. 3d 774, 792-793 (S.D. Tex. 2021) (representation is “material if a reasonable person would attach importance to and be induced to act on the information” and granting summary judgment against plaintiffs’ fraud claims because “plaintiffs identify no evidence, other than . . . speculation”); *Van Buren v. Walmart, Inc.*, 611 F. Supp. 3d 30, 40 (D. Md. 2020), *aff’d*, 855 F. App’x 156 (4th Cir. 2021) (holding that “in cases of omission or non-disclosure like this one, ‘the non-disclosed fact must be material, which means it must be one on which a reasonable person would rely in making a decision’” and dismissing fraud claim because plaintiff “does not allege that had the omitted information been included, he would have made a different decision”) Plaintiffs’ motion should fail on this ground alone.¹

Plaintiffs’ motion should also fail because Plaintiffs do not point to *any* statements made by Torrent to MSP, its assignors, or the TPPs that MSP seeks to recover on behalf of—let alone any material misrepresentations. *See* Pl. Br. at 3-4. Nor could they—Emblem and SummaCare representatives both testified that they never received any representations from any TPP Trial Defendant. TPP Trial Defendants’ Omnibus Statement of Material Facts Not in Dispute (“Def. SUMF”)

¹ Plaintiffs also ignore that the element of materiality is generally considered a question for the jury rather than a question that can be determined as a matter of law. *See, e.g., Harper v. Russell*, 836 A.2d 513 (Del. 2003) (“Generally, materiality is an issue of fact to be determined by the jury”).

at ¶¶ 84-85 ([ECF No. 2571](#)). Plaintiffs cannot base their fraud claim on alleged misrepresentations made to just anyone—the misrepresentations must have been made to the plaintiffs bringing fraud claims in this trial. *See Wilson v. Dryvit Sys., Inc.*, 206 F. Supp. 2d 749, 756 (E.D.N.C. 2002), *aff'd*, 71 F. App'x 960 (4th Cir. 2003) (granting defendant's summary judgment motion because plaintiff's fraud claim "is based on misrepresentations . . . allegedly made to third parties"); *Nevada Power Co. v. Monsanto Co.*, 891 F. Supp. 1406, 1417-1418 (D. Nev. 1995) (granting summary judgment on fraud claims where plaintiff "admitted that it had no direct oral or written communications with [the defendant]").

In an attempt to establish a misrepresentation, Plaintiffs rely on two weekly reports—one for July 16-22, 2018, and another for August 13-19, 2018—containing inquiries Torrent received from consumers via a hotline and the responses Torrent's vendor, APCER, provided to consumers. *See* Torrent Exs. 16-17²; Pl. Br. at 4. These reports contain a handful of questions regarding whether Torrent's VCDs had been recalled (and multiple questions about other, irrelevant

² "Torrent Ex." refers to exhibits filed in support of Plaintiffs' Motion for Partial Summary Judgment on Fraud Against Torrent ([ECF No. 2559](#)). "Def Ex." refers to exhibits filed in support of Torrent Defendants' Motion for Partial Summary Judgment ([ECF No. 2570-1](#)) and TPP Trial Defendants' Omnibus Statement of Material Facts Not in Dispute ([ECF No. 2571](#)). "Torrent Def. Ex." refers to exhibits to be filed by Torrent in support of its Opposition to Plaintiffs' Motion for Partial Summary Judgment and its Response to Plaintiffs' Statement of Undisputed Material Facts.

drugs), and APCER's response that no VCDs manufactured by Torrent had been recalled at that time, and that Torrent was investigating the situation and in communication with the FDA. *See* Torrent Defendants' Response to Plaintiffs' Statement of Undisputed Material Facts (Torrent) In Support of Motion for Partial Summary Judgment ("Torrent Resp. to Pl. SUMF") at ¶¶ 41, 43; Torrent Ex. 16 at 4-13, 18-19, 24-26, 28; Torrent Ex. 17 at 10, 12-14, 17-18, 20. Although Plaintiffs suggest there was something false in these statements to consumers, all the inquiries Plaintiffs point to occurred *prior* to Torrent's recall, and thus the statements that Torrent's VCDs were not recalled were true and accurate. *See id.*

Plaintiffs focus on one consumer inquiry received on August 17, 2018, at 2:51 PM ET, the same day that Torrent initiated its recall. Torrent Ex. 17 at 20; Pl. Br. at 4. As with other inquiries received before that date, APCER informed the consumer that Torrent's VCDs were not recalled by the FDA. *Id.* Contrary to Plaintiffs' suggestion, this statement was also true and accurate, because the recall was not finalized and announced until four hours later, at 7:08 PM ET. Torrent Resp. to Pl. SUMF at ¶ 43; Torrent Def. Ex. 1, TORRENT-MDL2875-00190336. Thus, this statement is likewise not a misrepresentation.

These true and accurate statements cannot be misrepresentations, let alone material misrepresentations. *See Trana Discovery, Inc. v. S. Rsch. Inst.*, 915 F.3d 249, 254 (4th Cir. 2019) (affirming summary judgment because plaintiff "has not

explained how the true statements . . . could have constituted a misrepresentation at all, much less a negligent one”); *Cnty. Hosp. of the Monterey Peninsula v. Aetna Life Ins. Co.*, 119 F. Supp. 3d 1042, 1048 (N.D. Cal. 2015) (granting motion for summary judgment on negligent misrepresentation claim where defendant’s statement “cannot constitute a misrepresentation of a past or existing material fact” because the statement—that the patient was a member of Aetna’s health insurance plan and that the patient was eligible to receive services—was a true statement).

Plaintiffs also argue, without basis, that Torrent made misrepresentations by “continu[ing] to misrepresent that its valsartan product was the FDA approved formulation that complied with the compendial requirements.” Pl. Br. at 4. Tellingly, Plaintiffs do not offer a single citation to support this assertion. *Id.* The opposite is true: the record reflects that Torrent’s VCDs complied with compendial requirements. *See* Def. SUMF ¶¶ 31, 98, 101.

Because Plaintiffs have failed to establish any misrepresentation made by Torrent and have not even attempted to establish that any alleged misrepresentation was material, their motion must be denied.

II. PLAINTIFFS HAVE NOT ESTABLISHED THAT TORRENT ACTED WITH SCIENTER.

As the Court has recognized, to prove a fraud claim for TPP Fraud Subclass Group C, Plaintiffs must prove, at a minimum, that Torrent had “knowledge of falsity” of any alleged false statements. [ECF No. 2261](#) at 32; *see also* [ECF No.](#)

[2570-1](#) at 3 n3. Additionally, certain jurisdictions in TPP Fraud Subclass Group C (Iowa, Louisiana, North Carolina, South Dakota, Virginia, and D.C.) require even greater culpability—specifically, an intent to deceive beyond mere knowledge.³ Plaintiffs ignore this higher standard, and present no evidence that Torrent had an intent to deceive in addition to knowledge of falsity. Plaintiffs’ motion should therefore be denied, at least as to the jurisdictions with a higher standard.

Even as to the states with a lesser standard, Plaintiffs still fail to establish as a matter of law that Torrent had knowledge of falsity. Plaintiffs’ arguments rely entirely on misrepresentations of the evidence. Plaintiffs argue that Torrent had knowledge that its VCDs contained NDMA because on August 3, 2018, ZHP informed Torrent that API manufactured using the Old Process contained trace amounts of NDMA. Pl. Br. at 4. However, the August 3 notification from ZHP did not contain any information about whether Torrent’s VCDs contained trace amounts of NDMA—it only addressed the API. Def. Ex. 54, TORRENT-

³ See *Kitt v. Cap. Concerts, Inc.*, 742 A.2d 856, 860 (D.C. 1999) (“The essential elements of common law fraud” include “the intent to deceive”); *Seibert v. Noble*, 499 N.W.2d 3, 7 (Iowa 1993) (“Among the elements of fraud is an intent to deceive, which the other party relies upon with resulting damages to the relying party.”); *Chateau Homes by RJM, Inc. v. Aucoin*, 97 So. 3d 398, 404 (La. App. 5 Cir, 2012), writ denied, 98 So. 3d 872 (La. 2012) (“For purposes of the tort of fraud, the intent to deceive is a specific intent.”); *Forbis v. Neal*, 361 N.C. 519, 526–27 (2007) (actual fraud requires an “intent to deceive”); *Est. of Johnson ex rel. Johnson v. Weber*, 898 N.W.2d 718, 729 (S.D. 2017) (fraud requires proof the defendant “made the representation with intent to deceive”); *Owens v. DRS Auto. Fantomworks, Inc.*, 288 Va. 489, 497 (2014) (fraud requires “intent to mislead”).

MDL2875-00143643. This notification does not confirm the existence or amounts of NDMA in Torrent's VCDs and does not equate to Torrent having actual knowledge that its product contained NDMA.

Plaintiffs' own briefing acknowledges this, noting that it was not until August 17, 2018—the day Torrent began its recall—that the FDA informed Torrent that five of its batches contained trace amounts of NDMA. *See* Plaintiffs' Statement of Undisputed Material Facts (Torrent) ("Pl. SUMF") at ¶ 16 ([ECF No. 2560](#)). This is the first date on which Plaintiffs could credibly allege that Torrent knew that its VCDs contained trace amounts of NDMA, and on that same day Torrent recalled those five batches from the market. *Id.* at ¶ 17. Knowledge that the VCDs may be at risk of contamination is not the same as knowing or believing that the VCDs were actually contaminated. *See Harris v. Pfizer Inc.*, 586 F. Supp. 3d 231, 241 (S.D.N.Y. 2022) (finding evidence that a defendant was notified that nitrosamines had been detected in other drugs in 2018 only demonstrated defendant may have known there was a risk of contamination, but did not establish defendant knew or believed the drug to be contaminated).

Plaintiffs' motion must be denied because Plaintiffs cannot establish that Torrent had actual knowledge of the presence of NDMA prior to receiving the FDA's test results on August 17, 2018, or that Torrent acted with an intent to deceive customers between August 3 and August 17, 2018.

III. PLAINTIFFS CANNOT ESTABLISH THE REMAINING ELEMENTS OF A FRAUD CLAIM AS A MATTER OF LAW.

Plaintiffs' arguments with respect to the remaining elements of a fraud claim are even more tenuous than their arguments for a misrepresentation or knowledge or intent to deceive. In lieu of presenting any evidence or case law to support their positions, Plaintiffs simply assert baseless conclusions on the remaining elements and ask the Court to agree with their conclusions as a matter of law.

Instead of offering evidence to meet their burden of establishing that Torrent intended to have consumers rely on some alleged misrepresentation, Plaintiffs make several leaps in logic that they characterize as evidence. Plaintiffs first contend that "if Torrent told customers that it is in the midst of initiating a recall on valsartan product, customers would immediately stop buying the product and ask to switch to another manufacturer's valsartan." Pl. Br. at 4-5. Plaintiffs offer no support for this statement and no explanation for how Torrent (or Plaintiffs) could possibly know what customers would do, let alone that Torrent did know what customers would do and made some decision based on that knowledge.

Plaintiffs next contend that "tell[ing] customers that Torrent's valsartan is not recalled" was the "only way to protect sales and profits," a sweeping allegation based on two emails. Pl. Br. at 5. Critically, neither of these emails say anything about "protect[ing] sales and profits," nor do they say that telling customers the truth (that Torrent's VCDs were not subject to recall prior to 7:08 PM ET on

August 17, 2018) was “the only way to protect sales and profits.” *See* Torrent Resp. to Pl. SUMF at ¶¶ 62-63. In fact, one of the statements Plaintiffs suggest came from Torrent was made by ZHP. *See* Torrent Ex. 20; Torrent Resp. to Pl. SUMF at ¶ 62. And both emails Plaintiffs cite to are from July 2018—before ZHP first notified Torrent that trace amounts of NDMA were detected in Valsartan API manufactured with the Old Process, and before Torrent initiated a recall. Thus, telling customers that Torrent’s VCDs were not recalled was an accurate statement, and Torrent could not have even considered sales or profits as part of a recall that had not yet happened. *See id.* at ¶¶ 62-63. Plaintiffs have not shown that there is no genuine issue of material fact as to this element.

Plaintiffs take a similar approach with the element of reliance. Instead of offering any case law or evidence that TPPs relied on a specific statement by Torrent, Plaintiffs simply assert that reliance is established as a matter of law because “[n]o TPP would have been able to purchase the contaminated valsartan if the truth had been told.” Pl. Br. at 5. Setting aside the fact that this does not come close to establishing reliance as a matter of law, Plaintiffs’ position is flatly contradicted by the record: there is no evidence in this case that TPPs relied on any statement from Torrent. SummaCare’s corporate representative testified that SummaCare does not have any relationship with manufacturers like Torrent, and EmblemHealth’s representative acknowledged that she was unaware of any

communications or representations regarding VCDs from the TPP Trial Defendants. *See* TPP Trial Defendants’ Omnibus Motion for Summary Judgment (“Def. Br.”) at 6-7, 16-17 ([ECF No. 2562-1](#)); Def. SUMF ¶¶ 84-85.

Plaintiffs likewise baselessly assert that “Plaintiffs were certainly damaged by purchasing adulterated, contaminated valsartan” because “if the truth had been told that could never have happened, since the contaminated valsartan could not have been sold.” Pl. Br. at 5. Once again, Plaintiffs offer no case law or evidence to support this conclusion. Contrary to Plaintiffs’ suggestion, the elements of causation and damages are not foregone conclusions. As explained in the TPP Trial Defendants’ Omnibus Motion for Summary Judgment, the TPPs were not harmed because they received exactly what they paid for: effective blood pressure medication for their members. Def. Br. at 24-28. Nor can Plaintiffs establish that any of Torrent’s alleged misstatements caused Plaintiffs’ purported losses. *Id.* at 28-31. And finally, Plaintiffs have no cognizable damages theory for a variety of reasons. *Id.* at 31-37.

Because Plaintiffs have not come close to meeting their burden on the remaining elements of a fraud claim, Plaintiffs’ motion must be denied.

CONCLUSION

For the foregoing reasons, Torrent respectfully requests that the Court deny Plaintiffs’ motion for partial summary judgment.

Dated: January 22, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Alexia R. Brancato, an attorney, hereby certify that on January 22, 2024, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Alexia R. Brancato
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